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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,235	10/27/2003	N. Sandor Racz	2102-4389US	3743

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EXAMINER	
CAMPBELL, VICTORIA P	
ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
03/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/694,235	RACZ ET AL.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-34* is/are pending in the application.

4a) Of the above claim(s) *7,10,11,13,19,20,22 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,12,14-18,20,21,23,25 and 27-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office Action following the Request for Continued Examination based on the 10/694235 application filed October 27, 2003. Claims 1-6, 8, 9, 12, 14-18, 20, 21, 23, 25, and 27-34 as presented in the reply filed January 26, 2009 are currently pending and considered below.

Response to Amendment

1. In response to applicant's amendment to claim 2, the examiner hereby withdraws the previous objection to the claims.

Claim Objections

2. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It appears that the subject matter of claim 15 was amended into independent claim 1 and therefore the examiner has addressed it's limitations with respect to claim 1 in the below rejection.

3. Claim 18 objected to because of the following informalities: line 4 of the claim recites the limitation "said first structure" which lacks antecedent basis. Examiner has interpreted the phrase to mean --said first attach structure--. Appropriate correction is required.

4. Claim 30 objected to because of the following informalities: it ends in two periods instead of one, and contains the phrase "said flexible needle" which lacks antecedent basis. Examiner has interpreted this phrase to mean --said flexible needle catheter--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 8, 9, 12, 14-18, 20, 23, 25, 27-29, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by USPGPub 2002/0099335 A1 to Zohmann.

Regarding claims 1-4, 6, 8, 9, 12, 14, 16, 32, and 33, Zohmann teaches a flexible needle catheter (6; every medical instrument, especially those comprised of a thin tube of any material, will have some degree of flexibility) defining a hollow bore for conveying medicating agent therethrough (Paragraph [0057]; although the introducer of Zohmann is not used in fluid delivery, it is capable of that function, and also houses a needle through which fluid is delivered, and it therefore passes through the introducer lumen as well), said flexible needle catheter having a proximal end defining a leading edge (74); a support needle (4) releaseably secured to said flexible needle catheter (Paragraph [0055]), said support needle being disposed within said hollow bore of said flexible needle catheter (Fig. 1), and having a first end (52) having a pencil-point tip (54;

applicant suggests that a "pencil-point" tip can not be blunt in any way, however, the examiner notes that a pencil-point in and of itself is not necessarily sharpened, and therefore pencil-point also encompasses blunted tapered tips, such as the one shown in Zohmann) and defining a hollow lumen (Paragraph [0052]) and an opening defined proximate said first end (53) which communicates the environment with said lumen, said support needle being dimensioned such that the first end of said support needle, as well as the opening, are positioned outside said bore (Fig. 1); and a solid stylet (2), releaseably secured within said lumen (Paragraph [0053]) in a first condition to preclude access from the environment to the lumen via the opening (Fig. 1). Zohmann further teaches that the leading edge of the flexible needle catheter is proximate and adjacent the tip of the support needle (Fig. 1), that the flexible needle assembly provides feedback to indicate dural puncture (Paragraph [0016]), that the support needle has a support hub (40) with a first attach structure (45) and a detach structure (47) and the flexible needle catheter has a hub (60), a second attach structure (62) and a detach structure (67). Zohmann further discloses a hub (40) capable of being secured to the patient, as well as a kink sleeve disposed about a portion of the flexible needle (65).

Regarding claims 16-18, 20, and 23, Zohmann teaches a flexible spinal needle assembly comprising: a flexible needle (6), and a support needle (4) having a proximal end (40) and a pencil-point tip (54; see note above on pencil-point) at the distal end (52), said support needle releaseably secured to said flexible needle (Paragraph [0055]) to resist relative motion between a distal end of said flexible needle and said tip during insertion; wherein said flexible needle is carried exterior to said support needle (Fig. 1).

Further, Zohmann teaches a flexible needle of sufficient length to be extended into the dura mater after extraction of a support needle, as well as a support hub (40) on the proximal end of said support needle having a first attach structure (45) and a flexible needle hub (60) on the proximal end of the flexible needle having a second attach structure (62), configured to interface removably with said first attach structure (Paragraph [0055]). Zohmann also teaches that the flexible needle assembly provides feedback to indicate dural puncture (Paragraph [0016]) and a kink sleeve disposed about a portion of the flexible needle (65).

Regarding claim 25, Zohmann teaches a flexible spinal needle assembly comprising: a support needle (4) having a pencil-point tip (54; see above note); a flexible needle body (6) comprising an elongated hollow tube (Paragraph [0057]) configured to be slidably mounted on an exterior of said support needle (Fig. 1); and a kink sleeve (65) disposed on a portion of said flexible needle body.

Regarding claim 27, Zohmann teaches a flexible spinal needle assembly comprising: a support needle (4) having a pencil-point tip (54; see above note) and a hollow bore (Paragraph [0052]); and a flexible needle (6) slidably mounted on an exterior portion of said support needle such that said first end of said support needle protrudes from said flexible needle (Fig. 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann in view of USPN 5,116,323 to Kreuzer et al.

Zohmann discloses the invention of claims 4 and 16 as described above, however Zohmann is silent to the connections being a luer lock. Kreuzer et al disclose a catheter assembly having luer lock connections between the catheter and needle structures. It would have been obvious to one of ordinary skill in the connector art to

modify the friction fit connection of Zohmann with a luer lock connector as taught by Kreuzer et al in order to provide an improved and more secured connection between the catheter and the needle.

11. Claims 28, 29, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann in view of USPN 5,250,035 to Smith et al.

Zohmann teaches the limitations of claims 1, 27, and 33 as described above, but fails to teach or disclose that the needle is comprised of medical grade plastic material, that the first end of the flexible needle catheter is tapered, or that the leading edge of the flexible needle catheter is perpendicular to the axis of the support needle. However, Smith et al teach a cannula and stylet system analogous to the flexible needle catheter and support needle system of Zohmann wherein the cannula (24) and stylet (26) are comprised of medical grade plastic (Abstract), and wherein the leading edge of the cannula is tapered and perpendicular to the long axis (Fig. 11). At the time of invention, it would have been obvious to one having ordinary skill in the art to combine the material of Smith et al with the system of Zohmann et al because medical grade plastics were well known at the time of invention and use of a known material is a design choice that would have been obvious to anyone of ordinary skill in the art. It would have been obvious to combine the outer catheter design of Smith et al with the system of Zohmann et al in order to provide a device that is less damaging to the patient upon insertion.

12. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zohmann in view of USPGPub 2005/0070881 A1 to Gribbons et al.

Zohmann teaches the limitations of claim 1 as disclosed above, but fails to teach or disclose a flat ribbon internal spring or metal band in the first end of the flexible needle catheter. Gribbons et al teach a flat metal ribbon or band (140) within the body of a catheter in order to provide support. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the flat metal band of Gribbons et al to the tip of the flexible needle catheter of Zohmann in order to further stabilize the tip to prevent bending during the insertion process.

Response to Arguments

13. Applicant's arguments filed January 26, 2009 have been fully considered but they are not persuasive.

14. Regarding applicant's arguments drawn to the blunt tip of Zohmann, the use of the introducer of Zohmann in fluid delivery, and the flexible nature of the catheter, the examiner directs the applicant to the rejection above where the application of the art has been more thoroughly explained.

15. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the method by which certain functions of applicant's device are achieved) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner further notes that although Zohmann is not intended for the same explicit function as the instant

invention, it would be capable of performing the functions as claimed by applicant and therefore meets all of the structural limitations of the instant claims.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
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